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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,458	11/28/2003	Leslie William Organ	BEW-005	9862

959 7590 03/14/2006

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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DRYDEN, MATTHEW DUTTON

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/724,458	<b>Applicant(s)</b> ORGAN ET AL.	
	<b>Examiner</b> Matthew D. Dryden	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-15 and 19-22 is/are rejected.
- 7) ☒ Claim(s) 4-6, 16-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Faupel (5415164).

Regarding claim 1, Faupel discloses a method comprising:

providing an electrode array containing a plurality of electrodes capable of being electrically coupled to the body pad (see Column 5, lines 8-10),

making an electrode assessment measurement with the electrode array (see Columns 7-8, lines 55-32),

determining whether the plurality of electrodes are suitably coupled to the body part based on the electrode assessment measurement (Columns 7-11, lines 55-33),

making a diagnosis measurement with the electrode array (see Columns 14-16, lines 26-12),

obtaining an electrical property of the body part based on the diagnosis measurement (see Columns 14-16, lines 26-12), and

diagnosing the possibility of disease based on the electrical property of the body part.

Art Unit: 3736

Regarding claim 13, Faupel discloses an apparatus for screening and diagnosing comprising:

an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part (see Column 7, lines 36-39),

a first measurement unit for making an electrode assessment measurement with the electrode array (see Column 7, lines 36-54, wherein the electrode array and shorting strip are used for the measurement),

an electrode assessment module for determining whether the plurality of electrodes are suitably coupled to the body pad based on the electrode assessment measurement (see Columns 7-8, lines 55-33, wherein the CPU and chip control and comprise the electrode assessment module),

a second measurement unit for making a diagnosis measurement with the electrode array (see Column 12-14, lines 56-25),

an electrical property module for obtaining an electrical property of the body part based on the diagnosis measurement, wherein the electrical property is used to diagnose the possibility of disease (see Columns 13-14, lines 28-25).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-15, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Organ (6122544) in view of Dempsey et al (5419337). Organ discloses the claimed method and invention except for providing an electrode assessment measurement unit and module with the electrode array and determining whether the electrodes are suitably coupled. Organ discloses an apparatus and method for detecting and diagnosing diseases comprising an electrode array containing a plurality of electrodes capable of being electrically coupled to the body part, making a diagnosis measurement, obtaining an electrical property of the body part, and diagnosing (see Columns 4-11, lines 14-46). Dempsey et al teaches it is known to provide an electrode assessment measurement with an electrode system to determine the quality of application to the body to eliminate artifact recordings that are characteristic of poor electrode application (see Column 5, lines 13-29). Also Organ teaches it is known to provide other electrodes with the system (see Column 6, lines 18-21) so substituting the electrode system of Dempsey et al would be obvious for making skin contact assessments. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ with an electrode assessment measurement, as taught by Dempsey et al, to determine the quality of application to the body to eliminate artifact recordings that are characteristic of poor electrode application.

Regarding claim 2, although not explicitly taught by Dempsey et al or Organ the method step of applying the electrode pairs to the body part before making an electrode assessment measurement is inherent, because the electrode assessment

Art Unit: 3736

measurement to determine the proper connection of the electrodes to the body would be pointless without connecting the electrodes to the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device and method of Organ, with a method step of applying the electrodes to the body before making an electrode assessment measurement because the purpose of the measurement is to provide the user with information of the quality of connection to the body.

Regarding claim 3, Organ discloses to inject current and measure the voltage after the current has been injected into a specific body part for a bipolar measurement, but does not disclose an electrode assessment measurement based on the readings. Dempsey et al teaches it is known to gather electrical data from a body part obtained from sensing electrodes and based on these readings, determine the quality of the connection to insure that patient hook-up is proper for a higher quality of measurement (see column 5, lines 13-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and device of Organ to include a method step of electrode assessment measurement after the current injection and voltage measurement, as taught by Dempsey et al, to make sure that patient hook-up is proper for a higher quality of measurement.

Regarding claim 7, Organ teaches to have the same number of injection pairs as measurement pairs (see Column 4, lines 35-38).

Regarding claim 8, see Column 4, lines 35-59.

Regarding claims 9-11, see Columns 6-8, lines 5-14.

Regarding claim 13, the device of Dempsey et al can be consider a module because a module is defined as a self-contained assembly of electronic components and circuitry, which Dempsey et al is for providing an indication of proper connection.

Regarding claim 14, see column 4, lines 35-39.

Regarding claim 15, the electrodes taught by Dempsey et al substituted as the measurement voltage electrodes in the device of Organ would be capable of measuring the voltage while the electrodes of Organ stimulate to make a bipolar measurement.

Regarding claims 19-23, see columns 6-11, lines 5-53.

Regarding claims 12 and 24, Organ as modified discloses the claimed method and invention except for the system comprising a GUI. Dempsey et al discloses a graphical user interface that includes the input of information by the user to select certain ECG strips for sampling by the computer (see Column 5, lines 13-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Organ with a user interface, as taught by Dempsey et al, to select certain ECG strips for sampling by the computer.

### ***Allowable Subject Matter***

Claims 4-6, 16-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,184,620 Cudahy et al discloses a method of using a multiple electrode pad assembly

U.S. Pat. No. 5,868,670 Randell discloses an article of manufacture for a biomedical electrode and indicator

U.S. Pat. No. 6,754,517 Nissila discloses an apparatus for measuring an electrocardiograph signal.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Application/Control Number: 10/724,458

Page 8

Art Unit: 3736

MDD

*McHickory*  
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PATENT EXAMINER  
10/11/2010